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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,594	11/12/1999	ELAZAR RABBANI	ENZ-58(DIV1)	1840

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ENZO DIAGNOSTICS, INC.
C/O ENZO BIOCHEM INC.
527 MADISON AVENUE 9TH FLOOR
NEW YORK, NY 10022

EXAMINER

TUNG, JOYCE

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 07/30/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/439,594

Applicant(s)

Rabbant et al.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/20/2002 and 5/5/2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 146-200 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 146-200 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8 and 13 6) ☐ Other:

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DETAILED ACTION

1. The amendment filed 3/20/2002 and 5/5/2003 has been entered. Following the entry of the amendment, claims 146-200 are pending.

Rejections and/or objected from the previous office action are hereby withdrawn. The following rejections are either newly applied or reiterated. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments with respect to claims 60-73 have been considered but are moot in view of the new ground(s) of rejection.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 146-200 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 60-68 of copending

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Application No. 09/104,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 146-200 are drawn to a process for detecting the presence of a specific target nucleic acid sequence involving using one or more first initial primers which has a first segment (I) being substantially complementary to a portion of said specific target nucleic acid sequence and (ii) capable of template dependent extension and a second segment being (I) substantially non-identical to said first segment, (ii) substantially identical to a portion of said specific target nucleic acid sequence (iii) substantially complementary to sequences that are synthesized by extension of the first segment of said first initial primers with said specific target nucleic acid sequence as a template wherein the first initial primers being capable of participation in the formation of a stem-loop structure after said specific target nucleic acid sequences is used as a template for extension. Furthermore, the method involves mixing and incubating the first primer with the reagents for the template dependent extension, forming at least one stem-loop structure and then detecting the presence of the stem-loop structures formed to determine the presence of the specific target nucleic acid.

Claims 60-68 of copending Application No. 09/104,067 are drawn a process for linearly amplifying a specific nucleic acid sequence involving the initial primer which has the same structure as the first initial primer used in the method of instant claims 146-200. Both the method of instant claims 146-200 and the method of claims 60-68 of copending Application No. 09/104,067 have similar method steps except that the instant invention is for detecting the presence of a specific target nucleic acid and the method of claims 60-68 of copending

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Application No. 09/104,067 is for amplifying a specific target nucleic acid which is part of the steps in the method of the instant claims 146-200. Thus it would render obvious over the genus method claims 60-68 of the copending Application No. 09/104,067.

While it is noted that the instant application is a divisional of the copending Application No. 09/104,067, the instant claims 146-200 are deemed not patentably distinct from claims 60-64 of the copending Application No. 09/104,067.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 146-200 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- a. Claims 146-200 are vague and indefinite because of the language "capable of" in claims 146, 166 and 183. It is unclear whether the first initial primer forms a stem-loop structure after said specific target nucleic acid sequence is used as a template for extension. Clarification is required.

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b. Claims 146-200 are vague and indefinite because of the language "derived from" in claims 146, 166 and 183. It is unclear because the segment is synthesized by the extension of the first segment of the first primer from the target nucleic acid used as a template, and the segment is not a derivative with the chemical modification of the extension of the first segment of the first primer from the target nucleic acid used as a template. By in large, the language "derived from" describes a derivative which is chemically modified chemical compound. Thus, it is suggested to clarify uncertainty.

Summary

7. No claims are allowable.

8. Any inquiries concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (703) 305-7112. The examiner can normally be reached on Monday-Friday from 8:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached at (703) 308-1119 on Monday-Friday from 10:00 AM-6:00 PM.

Any inquiries of a general nature or relating to the status of this application should be directed to the Chemical/Matrix receptionist whose telephone number is (703) 308-0196.

9. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Art Unit 1637 via the PTO Fax Center located in Crystal

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Mall 1 using (703) 305-3014 or 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Joyce Tung

J.T

July 18, 2003



**ETHAN WHISENANT
PRIMARY EXAMINER**